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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,128	07/17/2003	Birendra Nath Mallick	U 014722-6	5926
7590 12/08/2005			EXAMINER	
LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023			COLE, MONIQUE T	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,128

Applicant(s)

MALLICK ET AL.

Examiner

Monique T. Cole

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6 is/are allowed.
- 6) ☒ Claim(s) 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 12/9/2004 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 7 & 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall et al. "Glycosylated hemoglobins and glycosylated plasma proteins in the diagnosis of diabetes mellitus and impaired glucose tolerance" Diabetes Care, Mar-Apr., 7(2): 147-50 (1984) abstract (herein referred to as "Hall").
3. Hall teaches the measurement of glycosylated plasma proteins as quick, accurate and simple screening markers for the diagnosis of diabetes. It is noted that the instant claims are directed to the identification and/or diagnosis or REM sleep deprivation; however, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from

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the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Here, glycosylated protein is a recognized biological marker that is capable of performing the intended use of diagnosing REM sleep deprivation.

4. Claims 7 & 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wait et al. "Proteins of rat serum, urine and cerebrospinal fluid: VI. Further protein identifications and interstrain comparison," Electrophoresis, 22, 3043-3052 (2001) (herein referred to as "Wait").

Wait discloses alpha-1-Proteinase inhibitor 3 variant 1 in Table 2, spot 6. It is noted that the instant claims are directed to the identification and/or diagnosis or REM sleep deprivation; however, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Here, alpha-1-Proteinase inhibitor 3 variant 1 is a recognized marker that is capable of performing the intended use of diagnosing REM sleep deprivation.

Allowable Subject Matter

5. Claims 1-6 are allowed.

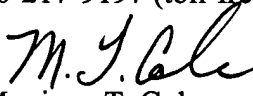
6. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest where a protein obtained from a blood sample is used as a marker; electrophoresis is performed; and a comparison of the samples is made where a reduction of ~200kDa protein band is indicative of a condition.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 571-272-1255. The examiner can normally be reached on Monday, Tuesday & Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Monique T. Cole
Primary Examiner
Art Unit 1743

mtc